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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,418	02/19/2002	Maria Dalko	010830-121	9294

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EXAMINER
DAVIS, RUTH A

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,418	DALKO ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *18-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 – 8 and 11 – 17 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that there was no distinction made between groups I and III, therefore the search would be reasonable to include the method of making the composition.

This is not found persuasive because the composition of ascorbic acid and a support could be made by other methods, for example by combining a solution of ascorbic acid with water. Further, the methods of groups III, IV and V are independent and distinct since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone. The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

Regarding claims 9 – 10 of group II, the restriction requirement is withdrawn because there is not an undue burden on examiner. In addition, the species election is withdrawn and all species have been considered. (i.e., each species named in the Markush groups of claims 4 and 6.)

The requirement between groups I:III, I:IV and I:V is still deemed proper and is therefore made FINAL.

Claims 1 – 17 have been considered on the merits.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 – 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a composition however are rendered vague and indefinite for reciting "capable of converting" because it is unclear if the enzyme must convert or merely may be able to convert the precursor.

In addition, it is unclear what the precursor is being converted to.

Claims 8 and 13 are rendered vague and indefinite for reciting "particularly" and "in particular" because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 13 is further indefinite for reciting "a total extract" because it is unclear what the phrase intends to encompass as it is not adequately defined by the claim or specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 – 3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fallick (US 5945447).

Applicant claims a topical composition comprising ascorbic acid and a support, wherein the ascorbic acid is obtained by contacting at least one ascorbic acid precursor (not ascorbic acid esters) with at least one enzyme capable of converting the precursor. The precursor is at least one substrate or is a chemical or biological precursor of ascorbic acid and the enzyme originates from an extract of plant, animal, insect or microorganism.

Fallick teaches a topical composition comprising ascorbic acid and water (support) (abstract).

Although Fallick does not specifically teach the method by which the ascorbic acid is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though

the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Therefore, the reference anticipates the claimed subject matter.

6. Claims 1 – 3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hadas et al. (DERWENT 1993-068301).

Applicant claims a topical composition comprising ascorbic acid and a support, wherein the ascorbic acid is obtained by contacting at least one ascorbic acid precursor (not ascorbic acid esters) with at least one enzyme capable of converting the precursor. The precursor is at least one substrate or is a chemical or biological precursor of ascorbic acid and the enzyme originates from an extract of plant, animal, insect or microorganism.

Hadas teaches a topical composition comprising ascorbic acid and bases (support) (abstract).

Although Hadas does not specifically teach the method by which the ascorbic acid is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Therefore, the reference anticipates the claimed subject matter.

7. Claims 1 – 3, 8, and 16 – 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Perricone (US 5122536).

Applicant claims a topical composition comprising ascorbic acid and a support, wherein the ascorbic acid is obtained by contacting at least one ascorbic acid precursor (not ascorbic acid esters) with at least one enzyme capable of converting the precursor. The precursor is at least one substrate is a chemical or biological precursor of ascorbic acid and is 0.01 – 50% or 0.1 – 10% of the compositions total weight. The enzyme originates from an extract of plant, animal, insect or microorganism.

Perricone teaches a topical composition comprising at least 0.5 – 10% ascorbic acid or ascorbic acid precursors and carriers (support) (col.2 line 33-34).

Although Perricone does not specifically teach the method by which the ascorbic acid is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Therefore, the reference anticipates the claimed subject matter.

8. Claims 1 – 3 and 8 – 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Boussouira et al. (US 6153205).

Applicant claims a topical composition comprising ascorbic acid and a support, wherein the ascorbic acid is obtained by contacting at least one ascorbic acid precursor (not ascorbic acid esters) with at least one enzyme capable of converting the precursor. The precursor is at least one substrate or is a chemical or biological precursor of ascorbic acid. The enzyme originates from an extract of plant, animal, insect or microorganism, is a total extract, purified enzyme solution, immobilized on a matrix (sol-gel), is solid, liquid or freeze dried, or is in a controlled release device. The enzyme is 0.05 – 30% or 0.1 – 10% of the total weight; the precursor is 0.01 – 50% or 0.1 – 10% total weight. The enzyme and precursor are packaged separately, in separate compartments, are encapsulated, microencapsulated or in microgranules.

Boussouira teaches a topical composition containing at least one enzyme, a vitamin C (ascorbic acid) precursor and alcohol (a suitable support) (abstract, col.3, line 1-6). The enzyme is present from about 0.05 – 30%, preferably 0.1 – 10%, of the total composition (col.2 line 59 – 66) and the precursor is 0.1 – 50%, preferably 0.5 – 10% (col.3 line 33-37). The precursor and enzyme are packaged separately so that contact is not made until application (abstract, col.2 line 34-40, col.3 line 57-64), and the composition may be encapsulated, microencapsulated or in microgranules (col.4 line 9-12). Boussouira teaches that upon combing and applying, the enzyme hydrolyzes (converts) the precursors to the active vitamin (col.2 line 41 – col.3 line 1).

Although Boussouira does not specifically teach the method by which the ascorbic acid is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though

the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 – 3 and 8 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boussouira.

Applicant claims a topical composition comprising ascorbic acid and a support, wherein the ascorbic acid is obtained by contacting at least one ascorbic acid precursor (not ascorbic acid esters) with at least one enzyme capable of converting the precursor. The precursor is at least one substrate or is a chemical or biological precursor of ascorbic acid. The enzyme originates from an extract of plant, animal, insect or microorganism, is a total extract, purified enzyme solution, immobilized on a matrix (sol-gel), is solid, liquid or freeze dried, or is in a controlled release device. The enzyme is 0.05 – 30% or 0.1 – 10% of the total weight; the precursor is 0.01 – 50% or 0.1 – 10% total weight. The enzyme and precursor are packaged separately, in separate compartments, are encapsulated, microencapsulated or in microgranules.

Boussouira teaches a topical composition containing at least one enzyme, a vitamin C (ascorbic acid) precursor and alcohol (a suitable support) (abstract, col.3, line 1-6). The enzyme is present from about 0.05 – 30%, preferably 0.1 – 10%, of the total composition (col.2 line 59 – 66) and the precursor is 0.1 – 50%, preferably 0.5 – 10% (col.3 line 33-37). The precursor and enzyme are packaged separately so that contact is not made until application (abstract, col.2 line 34-40, col.3 line 57-64), and the composition may be encapsulated, microencapsulated or in microgranules (col.4 line 9-12). Boussouira teaches that upon combing and applying, the enzyme hydrolyzes (converts) the precursors to the active vitamin (col.2 line 41 – col.3 line 1).

Although Boussouira does not specifically teach the method by which the ascorbic acid is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though

the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Furthermore, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use an enzyme originating from plants, animals insects or microorganisms in liquid, solid or freeze dried form because it was standard practice in the art at the time the claimed invention was made.

12. Claims 1 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boussouira in view of Wheeler et al. (May 1998) and/or Berry et al. (US 2002/0012979).

Applicant claims a topical composition comprising ascorbic acid and a support, wherein the ascorbic acid is obtained by contacting at least one ascorbic acid precursor (not ascorbic acid esters) with at least one enzyme capable of converting the precursor. The precursor is at least one substrate; a chemical or biological precursor of ascorbic acid; or at least one of L-galactono-1, 4-lactone, l-gulono-1, 4-lactone, D-glucorono 1, 4 lactone, D-glucuronic acid, D-mannose, D-galacturonic acid, D-glucose, D-galactose, L-galactose or mixtures thereof, specifically L-galactono-1, 4-lactone. The enzyme is selected from L-galactono-1, 4-lactone dehydrogenase, l-galactose dehydrogenase, l-sorbosone dehydrogenase, l-gulono-1, 4 lactone oxidase and mixtures thereof, specifically L-galactono-1, 4-lactone dehydrogenase. Alternatively the enzyme originates from an extract of plant, animal, insect or microorganism; or is a total extract, purified enzyme solution, immobilized on a matrix (sol-gel), is solid, liquid or freeze

dried, or is in a controlled release device. The enzyme and precursor are packaged separately, in separate compartments and are encapsulated, microencapsulated or in microgranules. The enzyme is 0.05 – 30% or 0.1 – 10% of the total weight and the precursor is 0.01 – 50% or 0.1 – 10% total weight.

Boussouira teaches a topical composition containing at least one enzyme, a vitamin C (ascorbic acid) precursor and alcohol (a suitable support) (abstract, col.3, line 1-6). The enzyme is present from about 0.05 – 30%, preferably 0.1 – 10%, of the total composition (col.2 line 59 – 66) and the precursor is 0.1 – 50%, preferably 0.5 – 10% (col.3 line 33-37). The precursor and enzyme are packaged separately so that contact is not made until application (abstract, col.2 line 34-40, col.3 line 57-64), and the composition may be encapsulated, microencapsulated or in microgranules (col.4 line 9-12). Boussouira teaches that upon combing and applying, the enzyme hydrolyzes (converts) the precursors to the active vitamin (col.2 line 41 – col.3 line 1).

Although Boussouira does not specifically teach the method by which the ascorbic acid is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Furthermore, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use an enzyme originating from plants,

animals insects or microorganisms in liquid, solid or freeze dried form because it was standard practice in the art at the time the claimed invention was made.

Boussouira does not teach the composition with the claimed enzymes and precursors. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use any of the claimed precursors and enzymes because they were known compounds of ascorbic acid synthesis. In support, Wheeler teaches that ascorbic acid precursors l-galactose and l-galactono-1, 4-lactone are converted to ascorbic acid by l-galactose dehydrogenase (abstract). Specifically Wheeler teaches the most effective precursor of ascorbic acid is l-galactono 1, 4 lactone which is converted by l-galactono 1,4 lactone dehydrogenase (p.365). In addition, Berry teaches ascorbic acid is produced when activity of l-galactose dehydrogenase and l-galactono lactone dehydrogenase is increased (0006) in the presence of ascorbic acid precursors l-galactose and l-galactono lactone (0041). Other ascorbic acid precursors that are converted include l-galactose, l-galactono lactone, d-glucose, d-galactose, d-galacturonic acid, d-glucurono lactone (table 6), d-mannose, l-gulono lactone, and d-glucoronic acid (table 8). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wheeler and/or Berry to use the claimed precursors and enzymes in the composition of Boussouira with a reasonable expectation for successfully obtaining an effective topical composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
December 18, 2002

LEON B. LANKFORD, JR.
PRIMARY EXAMINER